

9.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K031257

General Provisions	Trade Name: RITA® Model 1500X Electrosurgical RF Generator Common/Classification Name: Electrosurgical cutting and coagulation device
Name of Predicate	RITA Medical Systems Inc. – Model 1500 & Model 2500 Electrosurgical RF Generator
Classification	Class II
Performance Standards	Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.
Intended Use	The Model 1500X Electrosurgical RF Generator and accessories are indicated for use in percutaneous, laparoscopic, and intraoperative coagulation and ablation of soft tissue, including the partial or complete ablation of non-resectable liver lesions and the palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard pain therapy.
Device Description	<p>The Model 1500X Electrosurgical RF Generator is designed to provide monopolar radiofrequency (RF) energy. The RF Generator is a 150/200 W electrosurgical generator specifically designed for use with RITA electrosurgical devices. It can read multiple temperature sensors and includes impedance and power monitoring to assist the physician in monitoring and controlling the ablation.</p> <p>To use the system, the RF Generator is plugged into the wall outlet via the Power Cord. The electrosurgical device is connected to the RF Generator via the Main Cable. The Dispersive Electrode is placed on the appropriate location of the body and is connected to its port on the RF Generator. Once the system is successfully powered up, the user can set the parameters of the ablation such as the mode of operation, the ablation time, the target temperature, and the power delivery level. With the electrosurgical device placed in the tissue to be ablated and its electrodes deployed, RF power can be turned on. The system parameters are continuously monitored and displayed on the RF Generator. If the measured parameters are outside the acceptable limits, the RF energy delivery automatically stops and a message appears on the liquid crystal display (LCD). The RF energy delivery also automatically ceases once the ablation is completed based on the initial user-defined parameters. RF energy can be stopped at any time by pressing the RF ON/OFF switch.</p>
Performance Data	The Model 1500X RF Generator was subjected to a battery of electrical, mechanical, and software validation testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 2 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RITA Medical Systems Incorporated
c/o Ms. Denise Leung Klinker
Underwriters Laboratories Incorporated
1655 Scott Boulevard
Santa Clara,
CA 95050-4169

Re: K031257

Trade/Device Name: RITA® Model 1500X Electrosurgical RF Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 10, 2003
Received: April 21, 2003

Dear Ms. Klinker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

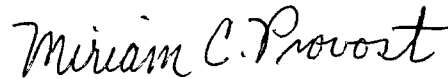
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

3.0 INTENDED USE**Indications for Use Statement**510(K) Number
(if known)K 031257

Device Name

Model 1500X Electrosurgical RF Generator

The RITA® System (RF generator and electrosurgical devices) supplies energy for use in electrosurgery and is indicated for use in percutaneous, laparoscopic, or intraoperative coagulation and ablation of soft tissue, including:

- the partial or complete ablation of non-resectable liver lesions and
- the palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard pain therapy.

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Prescription Use ☒ 510(k) Number K031257 OR Over the Counter Use ☐

(per 21 CFR 801.109)